

**REMARKS**

In the Office Action mailed December 19, 2006, Claims 1, 2, 13-24, 29-33 and 38-65 were pending for consideration. Claims 40-41 have been canceled and claims 44-65 are withdrawn from consideration. All of the claims were objected to and/or rejected on various statutory grounds, each of which is addressed in turn below. By the present amendment, Claims 1, 2, 17, 32, 33, 38, and 43 have been amended. Specifically, claim 1 has been amended to provide additional clarity with respect to the terms “caprylic acid mono/diglycerides and mono- and diacetylated monoglycerides.” Claims 1, 32, and 33 have each been similarly amended to limit the release modulators of the claim. Support for the amendments can be found in the published specification in paragraphs [0062] to [0065]. Claim 2 has been amended to correct the spelling of simvastatin. Claim 17 has been amended to correct the dependency and provide proper antecedent basis for all of the terms of the claim. Claim 31 has been amended to correct the spelling of amiodarone and to add the drugs topiramate and nimodipine. Support for the new drugs can be found in the published specification [0041]. Claim 43 has both been amended to correct their dependency and claim 48 has also been amended to enhance the grammatical clarity of the claim. Applicants submit that no new matter has been added in the by the above described amendments.

It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the correctness of the Examiner’s rejection. Accordingly, Claims 1, 2, 13-24, 29-33, 38-39, and 42-43 remain pending. Applicants respectfully submit that the present claims are allowable over the Patel ‘192 reference, and that the rejections in view thereof are now moot.

### Objections to claims

Claims 2, 31, 37 and 40 were each objected to for various reasons. Claim 37 has been canceled. The Examiner has objected claims 2 and 31 for misspellings and claim 40 for grammatically awkward language. The Applicant's thank the Examiner for her diligence in identifying these issues. Each of the objected to claims has been amended as recommended by the Examiner in order to overcome the present objections. Applicants believe that such amendments are adequate to overcome the Examiner's objections

### 35 U.S.C. § 112 Rejections

#### First Paragraph

The Examiner has rejected claims 1-2, 13-24, 29-33 and 43 under U.S.C § 112, first paragraph for allegedly failing to comply with the written description requirement with respect to the phrase "a release modulator which synchronizes the release of the drug and the solubilizer." As described above, the Applicants have amended Claim 1 and claims 32 and 33 to include specific lists of release modulators which can used to accomplish the present invention. Applicants assert that the present amendment of the claims provides ample written description as required under 35 U.S.C. §112, first paragraph, and respectfully request that this rejection be withdrawn.

#### Second Paragraph

The Examiner has rejected claims 1-2, 13-24, 29-33 and 37-41 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Specifically, the Examiner rejected claim 1 for allegedly lacking clarity with respect to the phrase "capryllic acid mono/diglycerides and mono- and diacetylated monoglycerides." Additionally, the Examiner has rejected claim 1 for the use

of the phrase “200-8000 MW”. Applicants have amended claim 1 as described above in order to enhance the clarity of claim 1.

The Examiner also rejected claims 17-19 were rejected for an alleged lack of antecedent basis for the term “the period of time.” Claim 17 has been amended as described above, namely to alter the dependency of the claim and enhance the antecedent basis of the claim. As such the Applicants believe that each of the rejections by the Examiner under § 112, second paragraph should be withdrawn.

35 U.S.C. § 102 Rejections:

The Examiner has rejected Claims 1-16, 20-26, 28-36, 38-39, and 41-42 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,294,192 (hereinafter “Patel ‘192”), filed on February 26, 1999, in light of Stedman’s Medical Dictionary (1972, p.595 and 1400). Specifically, the Examiner has stated that although the cited reference “may not expressly acknowledge the “release modulating properties of the disclosed components” the cited reference allegedly anticipated the claims because “the prior art publication teaches a composition of identical physical components.” The Applicants assert that the presently pending claims are distinct from and patentable over the cited reference.

As presented in the previous office action, the present invention claims a pharmaceutical composition including a therapeutically effective amount of a drug; and a solubilizer selected from the group consisting of selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprates, caprylic acid mono/diglycerides,

and mono- and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides,  $\alpha$ -tocopherol,  $\alpha$ -tocopherol acetate,  $\alpha$ -tocopherol succinate,  $\alpha$ -tocopherol polyethyleneglycol (200-8000 MW) succinate,  $\alpha$ -tocopherol polyethylene glycol 400 succinate, d1- $\alpha$ -tocopherol polyethyleneglycol 1000 succinate, and d- $\alpha$ -tocopherol polyethyleneglycol 1000 succinate. The composition further includes a release modulator which synchronizes the release of the drug and the solubilizer, said release modulator is selected from the group consisting of methyl cellulose, a hydroxypropyl methylcellulose derivative, an acrylic polymer, a polyvinylpyrrolidone copolymer, a polyvinyl acetyl phthalate, a high molecular weight polysaccharide gum, hydrogenated vegetable oil, glycerol dibehenate, glycerol mono stearate, glycerol distearate,  $\alpha$ -tocopherol succinate,  $\alpha$ -tocopherol polyethyleneglycol succinate, sucrose distearate, cetyl ester wax, and mixtures thereof.

The '192 Patent does not teach a composition with release modulators which has the characteristic of being able to provide synchronized release of a drug and a solubilizer present in a single formulation. As such, the '192 patent does not teach each and every element of the present invention. Even assuming, *arguendo*, that the 192 Patent does coincidentally teach compositions having release rate modulators, the presently pending claims have been amended so as set forth specific solubilizers with which the modulators would be effective. Such a teaching is clearly not found in the '192 patent.

As discussed and demonstrated in during the interview with the Examiner on April 26, 2007, the mere presence of the same or similar compounds in a compositions does not necessarily impart to the composition the same properties. In support of this concept, the Applicants submit herewith an affidavit under 35 U.S.C. 1.132 which sets forth and discusses the

demonstration presented in the Examiner Interview and further elaborates the functional differences between the present invention and the cited reference.

In view of the arguments set forth above as well as the accompanying affidavit, the Applicants respectfully submit that the cited Patel '192 reference does not teach each and every element of the pending claims, and therefore it is respectfully requested that this rejection be withdrawn.

**CONCLUSION**

In view of the foregoing, the Applicants believe that Claims 1, 2, 13-24, 29-33 and 38-39 and 42-43 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 19<sup>th</sup> day of June, 2007.

Respectfully submitted,

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